AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2482-CN]

RIN 0938-AT82

Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer
Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement;
Delay of Inclusion of Territories in Definition of States and United States; Correction

ACTION: Final rule; correction

SUMMARY: This document corrects technical errors in the final rule that appeared in the November 19, 2021 **Federal Register** entitled, "Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States."

DATES: Effective December 20, 2021.

SUPPLEMENTARY INFORMATION:

FOR FURTHER INFORMATION CONTACT: Christine Hinds, (410) 786-4578.

I. Background

In FR Doc. 2021-25009 (86 FR 64819), the final rule entitled, "Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States" there were technical errors that are identified and corrected in this correcting document. These corrections are applicable as of December 16, 2021.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 64819 of the Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States final rule, we inadvertently omitted the delayed effective date of the revised definition of "Best price" at § 447.505(a), which was previously published in the December 31, 2020 **Federal Register** (85 FR 87000) in instruction 10.a..

B. Summary of Errors in the Regulatory Text

On page 64825, we inadvertently included amendatory instruction 3.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (the APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. In addition, section 553(d) of the APA mandates a 30-day delay in effective date after issuance or publication of a substantive rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements. Section 553(b)(B) of the APA authorizes an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. Similarly, section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date where good cause is found and the agency includes in the rule a statement of the finding and the reasons for it. In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements.

This document merely corrects technical errors in the Medicaid Program; Delay of
Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices
Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in
Definition of States and United States final rule. The corrections contained in this document are

consistent with, and do not make substantive changes to, the policies that were proposed, subject to notice and comment procedures, and adopted in the Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States final rule. As a result, the corrections made through this correcting document are intended to resolve inadvertent errors so that the rule accurately reflects the policies adopted in the final rule. Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the Medicaid Program; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the rule accurately reflects our policies as of the date they take effect. Further, such procedures would be unnecessary because we are not making any substantive revisions to the final rule, but rather, we are simply correcting the Federal **Register** document to reflect the effective date for the policies that we previously proposed, received public comment on, and subsequently finalized in the final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

IV. Correction of Errors

In FR Doc. 2021-25009 (86 FR 64819), make the following corrections:

A. Correction of Errors in the Preamble

On page 64819 in the second column, correct the DATES section to read:

DATES: This rule is effective December 20, 2021. As of December 20, 2021, the effective date of amendatory instruction 10.a. of the final rule published December 31, 2020 at 85 FR 87000 of January 1, 2022 is delayed until July 1, 2022.

B. Correction of Errors in the Regulatory Text

§ 447.505 [Corrected]

On page 64825, remove instruction 3.

Karuna Seshasai,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2021-27452 Filed: 12/16/2021 8:45 am; Publication Date: 12/17/2021]